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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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TITLE OF INVENTION (280 characters max)

DEVICE AND METHOD FOR AN AUTOMATED E.E.G. SYSTEM FOR AUDITORY EVOKED RESPONSES

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Respectfully submitted, Date: June 19, 2003

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U.S. PROVISIONAL PATENT APPLICATION

DEVICE AND METHOD FOR AN AUTOMATED E.E.G. SYSTEM FOR AUDITORY EVOKED RESPONSES

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DEVICE AND METHOD FOR AN AUTOMATED E.E.G. SYSTEM FOR AUDITORY EVOKED RESPONSES

Field of the Invention

[0001] The present invention relates generally to a method and apparatus for capturing electroencephalogram (EEG) signals. More particularly, the present invention provides a method and describes a system for the purpose of diagnosing dyslexia, and similar neurological conditions such as autism, schizophrenia, etc., by capturing brain waves produced while processing a preprogrammed auditory stimulus.

Background of the Invention

[0002] Dyslexia is an inborn condition characterized by abnormal brain physiology or "defective wiring". Detailed studies of the brains of known dyslexics show a marked difference from normal brains. This physical difference has been detected with a variety of brain imaging modalities including; MRI, CT, and PET. The pathophysiology is characterized by a disruption in left hemisphere posterior reading systems, primarily in left temporo-parieto-occipital brain regions, with a relative increase in brain activation in frontal regions (Shaywitz, et al, "Dyslexia Specific Reading Disability", Pediatrics in Review, Vol. 24, No. 5, May 2003).

[0003] Dyslexia effects about 10-15% of the population to varying degrees and manifests as difficulty reading, inability to concentrate, and various other learning disabilities. Surprisingly, dyslexia is unrelated to low I.Q. and is common in many successful and motivated people. Examples of recognized dyslexics include Einstein, Edison, Ford, Patton, da Vinci, Rockefeller, Churchill, Disney, and others (from www.dyslexia.com). Dyslexia is not a chemical imbalance or behavioral disorder like Attention Deficit Hyperactivity Disorder (ADHD) and can't be treated with drugs such as Ritalin as used in some ADHD children.

[0004] Typically, dyslexia is not diagnosed until between ages 5 and 8, usually after the child has fallen 2 grade levels behind in reading. By this time, much of the permanent damage to the child has already been done. Parents of dyslexic children

are often forced to endure the difficulties of raising a child who is has been labeled as "slow", "disruptive", or a "problem-child". Sometimes these dyslexic children are misdiagnosed as ADHD. These children may be put on drug therapy in hopes of controlling disruptive behaviors. While this may have some mitigating impact on the school system, this kind of therapy will have no beneficial direct effect on dyslexia itself. The longer-term negative effects include illiteracy, anti-social behavior, and low income.

[0005] Most current dyslexia screening tests measure obscure, anecdotal, action-response behaviors. Some tests include; posturography which measures balance strategies, bead threading which measures sequential memory, rhyming games which measure phonological awareness, and others. These tests can only be given to a child who is old enough to perform reading, puzzle solving, or other high-level assessment skills. None of these tests directly detect the underlying physical brain wiring defect. Poor performance on these tests could be attributed to causes other than dyslexia.

[0006] In 1929, the German psychiatrist, Hans Berger, announced to the world that: "it was possible to record the feeble electric currents generated on the brain, without opening the skull, and to depict them graphically onto a strip of paper… that this activity changed according to the functional status of the brain, such as in sleep, anesthesia, hypoxia (lack of oxygen) and in certain nervous diseases, such as in epilepsy." (Berger, H., "Uber das elektrenkephalogramm des menschen", Archiv fur Psychiatrie und NervenkranEheiten, 1929, 87:527-580). Berger named this new form of recording as the electroencephalogram (EEG).

[0007] EEG measurements from auditory evoked responses (AER) detect voltage potentials from the brain as the brain attempts to discriminate a sound. EEG's from dyslexic children show abnormally high peak voltages and signal latencies. These characteristics correlate to higher than normal energy requirements to process sounds and slower discrimination and sound-to-symbol mapping. The outward manifestations of which will primarily be difficulties reading and writing.

[0008] Recent evidence has shown that dyslexic brains can be remodeled or retrained to overcome the wiring defect (Simos, et al., "Dyslexia-specific brain activation profile becomes normal following successful remedial training", Neurology

2002;58:1203–1213). Many experts believe that intervention will be most effective early in a child's life ("A New Era: Revitalizing Special Education for Children and Their Families", President's Commission on Excellence in Special Education, July 1, 2002). Early detection is the key mitigating the lifelong effects of dyslexia.

[0009] Electroencephalograms or EEG's are voltage potentials measured on the scalp produced during brain activity where the magnitude of the voltage differentials is plotted versus time. An EEG system is composed of several discrete system components. The first component is a conductive electrode that is placed on the scalp generally in close proximity to an inactive part of the brain. This inactive or "reference" electrode is used as a reference for other "active" electrodes placed on the scalp in close proximity to processing areas of the brain. The electrodes are electrically connected to voltage amplifiers, bandpass filters, and various other electronic components generally used in processing electronic signals. In most current systems, the analog voltage signal is passed through an analog to digital converter where the signal is sampled at a user-controlled rate and converted to digital data. The digital data may then be stored on digital media for later processing.

[0010] The most important requirements for clinical application of EEG's were described in 1947 in patent 2,426,958 by Ulett; The electrode and placement technique associated therewith should be such that the electrode produces no artifacts; is easy to apply, keep on, and remove; and, it is relatively cheap in production and painless in its application and use.

[0011] More recently, clinical research has been conducted using evoked response potentials (ERP) wherein a stimulus is provided to a subject and an EEG is measured and recorded. Depending upon the location of the active electrode, the measured EEG may correspond to processing activity of the brain in response to a certain stimulus such as a sound, indicating that certain processing regions such as the auditory processing regions have responded to the stimulus. These EEG measurements are known as evoked response potentials (ERP).

[0012] One particular area of research with ERP has been dyslexia. Dyslexia is one of the most common psychological problems affecting between 5 and 15% of the population. Up to 80% of all people diagnosed with learning disabilities are dyslexic

(Shaywitz, et al, "Dyslexia Specific Reading Disability", Pediatrics in Review Vol.24 No.5 May 2003). The word dyslexia stems from "dys" meaning "difficulty" and "lexia" meaning "words. " While dyslexia is usually detected only after a child has a proven record of academic failure, it is actually an inborn condition characterized by defective "brain wiring" and is associated with a variety of other learning disabilities.

[0013] If diagnosed at all, dyslexia is typically detected in children between the ages of 5 and 8 after they have fallen two grade levels behind in reading. This difficulty in learning often results in the child being labeled "slow," leading to a significant self-esteem problem and permanent long-term psychological damage.

[0014] Dyslexia has a tremendous negative impact on the children who suffer with it, the parents who struggle with raising a child who is "slow" or "disruptive", the school system charged with the difficult task of educating these children and society as a whole that must bare the financial and social cost of illiteracy. However, if dyslexia could be detected early, so that a child could be effectively treated before entering school, the psychological damage resulting from being labeled "stupid and slow" could be avoided and he/she could take full advantage of their schooling and fulfill their full intellectual potential.

[0015] Current dyslexia screening methods can only be used in school-age children once they have developed reading, puzzle solving, and/or other high-level skills. These assessment methods generally measure obscure, anecdotal, action-response behaviors like bead threading which measures sequential memory, rhyming games that measure phonological awareness, posturography which measures balance strategies, and others. It is important to note that none of these methods directly detect the underlying physical defect in brain wiring which characterizes dyslexia. Not surprisingly, these methods often fail to provide an accurate diagnosis of dyslexia.

[0016] A body of research has been performed by Drs. Dennis and Victoria Molfese to develop and scientifically validate the use of ERP's to diagnose dyslexia in infants so that earlier and more effective intervention is possible. (Molfese, D., "Predicting Dyslexia at 8 Years of Age Using Neonatal Brain Responses", Brain and Language 72, 238-245 (2000); Molfese, et al, "Newborn and Preschool Predictors of Second-

Grade Reading Scores", Journal of Learning Disabilities, No. 6, November/December 2001, pp 545-554; and Molfese, et al, "The Use of Brain Electrophysiology Techniques to Study Language: A Basic Guide for the Beginning Consumer of Electrophysiology Information", Learning Disability Quarterly, Volume 24, Summer 2001, pp. 177-188). In particular, this research has identified optimum positions on the subject's scalp for picking up these characteristic electrical potentials and for identifying an ERP characteristic of dyslexia.

[0017] While this research into ERP diagnosis of dyslexia has been of scientific interest, diagnosis of dyslexia in infants is not common in a clinical setting. By contrast, hearing deficits affect only about 1 in 500 newborns whereas dyslexia affects 50 times as many children, yet the Universal Newborn Hearing Screening (UNHS) test is mandated in 38 states. Therefore, approximately 69% of the 4,000,000 children born in the U.S. each year have this UNHS test performed soon after birth. The UNHS test uses a similar EEG technology to measure brainwaves from the brain stem or "unconscious" part of the brain as a result of an auditory stimulus.

[0018] At least part of this disparity in clinical use is believed to be the testing equipment required for dyslexia ERP diagnosis. The UNHS test only verifies the connection between the ear and the brain stem. As such, a relatively simple diagnostic analysis is required to detect the presence of brain stem response to a sound. The dyslexia ERP diagnosis requires a more subtle comparison of characteristic waveforms for optimum auditory processing in the normal population compared to a sub-optimum auditory processing in the dyslexic population. Such sophisticated processing makes this analysis unpractical for the relatively untrained staff in a neonatal care unit.

[0019] Moreover, unlike UNHS testing where measurements from a single active electrode are used, dyslexia ERP testing requires a time consuming process of attaching and taking measurements from several electrodes. Not only does the test preparation and locating of electrodes require some expertise, so does recognition as to whether a sufficient signal is being detected for analysis to be performed. Even under the best of circumstances, the signal-to-noise ratio (SNR) of ERP is low.

[0020] Yet a further disincentive to clinical use of dyslexia ERP testing is the fact that a desired test population are newborn infants. Known electrode attachments and analysis equipment are cumbersome, imposing in appearance, with long and potentially dangerous wiring harnesses, tending to disconcert parents and other visitors to maternity wards who may witness the test.

[0021] Consequently, a significant need exists for a dyslexia testing device and method that is suitable for widespread clinical use.

Brief Summary of the Invention

[0022] The invention overcomes the above-noted and other deficiencies of the prior art by providing a screening device that is simple to use in a clinical environment. A headset is readily engageable to a head of an infant subject and positions an electrode on a reference location on the head, such as the forehead, and positions a signal electrode advantageously with regard to the infant's ear. This signal electrode is thus readily positioned proximate to the auditory processing locations on the infant's head to sense an Evoked Response Potential (ERP) after an auditory stimulus is given to the infant. Simplified electrode placement allows clinical use by those without having specific neurological training.

[0023] In one aspect of the invention, the headset device positions the electrodes for convenient data acquisition and further stores the ERP data after the auditory stimulus for later uploading via a communication link to a data analyzer. Thereby, the expense of a data analyzer is removed from the device, allowing one data analyzer to be more efficiently use to support a large number of devices. Moreover, the headset device is more portable and less intrusive for use in various clinical settings.

[0024] These and other objects and advantages of the present invention shall be made apparent from the accompanying drawings and the description thereof.

Brief Description of the Figures

[0025] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and, together with the

general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0026] FIG. 1 is a perspective view of an integrated Evoked Response Potential (ERP) headset for clinical screening for dyslexia in infants.

[0027] FIG. 2 is a close-up view of an electrode attached to one of the headset's flexible arms.

[0028] FIG. 3 is a functional block diagram of a controller of the headset of FIG. 1.

[0029] FIG. 4 is a block diagram of the headset, the data and power connection means, the Internet connection means, the data repository and analysis means, and the data transmitting means.

[0030] FIG. 5 is a flowchart describing a method to stimulate, capture, and analyze EEG's to diagnose dyslexia.

Detailed Description of the Invention

[0031] In the drawings where like members are given the same reference numeral, in FIG. 1, an integrated Evoked Response Potential (ERP) headset 10. Advantages of the headset 10 include embedded features that enable clinicians to readily perform an electroencephalogram (EEG) test without the necessity of extensive training. Portability of diagnostic data taking allows use whenever and wherever desired. Economy of use is achieved by centralized processing of the diagnostic data so that a great number of headsets 10 may be used without the necessity of expensive waveform processing equipment at each location. Collecting data from many screened individuals enables enhanced and improved the diagnostic algorithms to be created and implemented. Furthermore, the headset 10 includes features that speed its use while avoiding human error and the need for extensive training.

[0032] To these ends, the headset 10 incorporates a control module 12 that advantageously allows the headset 10 to be portable and to be used in a clinical setting by including pre-loaded or downloadable testing protocols managed by the control module 12, enhancing ease of use. The headset 10 further includes an elastic, semi-rigid frame 14, which contains the control module 12. In particular, the frame

14 automatically positions six conductive electrode plugs 16 via flexible arms 18 to specific positions 20 relative to the subject's ears correlating to portions of the brain responsiblc for auditory processing. This convenient positioning greatly simplifies thc generally accepted practice of manually positioning each electrode on the scalp in reference to a central point. A similar reference electrode plug 16′ is positioned by flexible arm 18′ to a forehead location 22 of the subject, this point selected for being relatively at an electrical ground potential relative to the auditory processing locations and for being readily accessible with a supine subject.

[0033] Each electrode plug 16, 16′ contacts the subject's skin via an electrode pad 24, 24′ that includes electrical contacts to pickup the voltage signal of the ERP. The frame 14 and flexible arms 18, 18′ exert a force respectively upon each electrode plug 16, 16′ and electrode 24, 24′ to achieve a good electrical contact. Each electrode pad 24, 24′ may be individually replaceable to ensure proper operation and/or sterilization requirements. Alternatively, a larger portion of the headset 10 may be replaceable for such reasons. Yet a further alternative may be that the electrodes 24, 24′ may be compatible with sterilizing agents, such as an alcohol wipe. The electrode pads 24, 24′ may support or incorporate an electrically conductive substance such as silicon or saline to enhance electrical contact. Alternatively or in addition, the electrode plugs 16, 16′ and electrode pads 24, 24′ may incorporate a pneumatic seal when manually depressed against the subject's skin, or even further include an active pneumatic suction capability to achieve good contact.

[0034] The frame 14 also supports ear cups 26 that position sound projectors 28 in front of the respective subject's ear. The headset 10 includes a speaker 30 for each ear that generates an auditory signal in response to an electrical signal from the control module 12. Each speaker 30 may be in a respective ear cup 26. Alternatively, each speaker 30 may be proximate to the control module 12, such as a piezoelectric transducer, that generates a sound that is directed through a pneumatic sound tube (not shown) to the sound projector 28 in the ear cup 26. This latter configuration may have advantages for having a replaceable ear cup assembly wherein active components are relegated to a reusable portion or where the active components are externally coupled to a passive, perhaps disposable headset.

[0035] When the headset 10 is used, simplified indications and controls 32 let the clinician know that the headset 10 is operational. For instance, an indication may be given that sufficient battery power exists, that the electronic components have passed a built-in test, etc. Thereby, the clinician, even with little specific training into the ERP waveform analysis, is able to readily perform the data acquisition on the subject.

[0036] Although the headset 10 may include all of the functionality required to perform a dyslexia ERP testing protocol, the headset 10 advantageously accepts an external electrical connector 34 at an interface 36 so that additional functionality may be selectively used. For instance, rechargeable batteries (not depicted in FIG. 1) in the headset 10 may be charged. The interface 36 may accept subject identification information to be linked with the diagnostic data taken. For instance, a personal computer, personal digital assistant, or a keyboard may be interfaced to the headset 10 as a means to input subject identification information. An illustrative input device, depicted as a barcode scanning wand 38, such as OPTICON PN MSH-220, is activated by a push button 40 to read a patient identification band 42. The illustrative wand 38 advantageously has a short reach to minimize the likelihood of misidentifying the subject being tested.

[0037] It should be appreciated by those skilled in the art having the benefit of the present disclosure that a hard-wired interface 36, such as a Universal Serial Bus (USB) interface, may be used as depicted or a wireless connection may be made, such as using the BLUETOOTH standard or other type of link.

[0038] Furthermore, a barcode identifier may be a one-dimensional or a two-dimensional barcode. Similar, the identifying information may be in the form of an embedded radio frequency (RF) target that puts off a unique return when energized by an RF carrier signal. Other types of identifying information may be used consistent with aspects of the present invention.

[0039] FIG. 2 depicts the flexible arm 18, 18′ supporting the electrode plug 16 annotated to denote resilient characteristics inherent so that a good electrical conduct is achieved. It will be appreciated that wiring or conductive ink applied to or formed therein may be used to electrical couple the electrode plug 16, 16′ to the control module 12.

[0040] FIG. 3 depicts an illustrative control module 12 of the headset 10 formed as an electronic circuit 50. It should be appreciated that the electronic circuit 50 may advantageously be produced in large-scale production as a custom Application Specific Integrated Circuit (ASIC) wherein all or many of these and other functions are incorporated into a single silicon wafer.

[0041] In the illustrative version, a number of discrete devices are used to perform the acquisition of ERP data. The electrode pads 24, 24' produce a low voltage signal that is amplified by amplifiers 52, such as BURR-BROWN OPA4347EA/250 Quad Op-Amps. The amplified signal therefrom is rccoived by an integrated memory 54, such as a TOSHIBA, Part. No. TC58128AFT, 128 MB 3.3V Flash Memory in a 48 Thin Small-Outline Package (TSOP) Surface-Mount Technology (SMT) package. The memory 54 receives inputs data from external devices, such as the barcode scanner 38 via the interface (e.g., USB port) 36. The memory 54 is also preloaded or uploaded with a testing protocol and stores a number of testing session data records so that the headset 10 may be repeatedly used prior to uploading results.

[0042] The processing is performed by a microcontroller 56, such as MICROCHIP PIC16C765-I/PT, which advantageously includes analog-to-digital (A/D) Converters and USB Communication capability. An example of the processing includes sending a predetermined number of audio signals of a predetermined pitch, volume and duration or a previously recorded and digitized sound, and recording the resultant ERP waveform.

[0043] The desired audio signals are produced by a digital sound card 58, such as by WINBOND ELECTRONICS, ISD4002-150E, "Single-Chip Voice Playback Device" that produce the audio signals on speakers 30. The electronic circuit 50 is powered by a power supply 60, such as an ULTRALIFE UBC502030 , Rechargeable 200mAh battery.

[0044] FIG. 4 depicts an dyslexia screening test system 70 that advantageously provides for economical testing, billing, long-term data storage and analysis for analysis refinement, follow-on therapeutic measures, and other features. To this end, the headset 10 may be in electrical communication with a hospital system 72 via a cable or wireless link 74 so that accomplishment of the dyslexia screening test is

noted for patient health records and for billing records. Also, the hospital system 72 may facilitate communication across a network, such as the Internet 76, to a remote processing facility, depicted as a data repository and analysis computer 78.

[0045] This data repository and analysis computer 78 allows for the most up-to-date waveform recognition techniques to be employed to diagnose a dyslexia condition. Moreover, the computer 78 may process a number of data from screening tests to make such analysis more cost effective. Moreover, historical data may be mined as recognition techniques improve to capture previously undiagnosed conditions or to otherwise correlate previous test results with other forms of data to further refine the diagnostic process. It should be appreciated that the analysis performed by the data repository and analysis computer 78 could further include neural net processing, wherein the neural net is trained to recognize a waveform characteristic of dyslexia or other conditions.

[0046] Positive, inconclusive, and/or negative screening test results may be forwarded to an appropriate recipient, such as a referral physician 78 for further diagnostic testing and/or therapeutic measures.

[0047] FIG. 5 depicts an illustrative method or sequence of operations for dyslexia screening performed by the test system 70 of FIG. 4. In block 100, the headset is disconnected from a hospital computer or other device after a previous upload of screening test data, download of an updated test protocol, and/or charging of the batteries in the headset. The headset is prepared for the next subject by ensuring that the headset is sterile and has operable electrodes. One way is as depicted in block 102 by attaching an unused electrode pad to each of the electrode arms.

[0048] With the headset ready, the headset is placed upon an infant subject's head. The frame of the headset simplifies placement by including ear cups and a forehead reference electrode that intuitively guide the clinician in proper placement (block 104). Simplified initiation of the test is provided by attaching a barcode scanner to the headset and depressing a control push button on the scanner (block 106). The headset interprets this button push and initiates a self-test to verify functionality to include sufficient power, good reception of an EEG signal from the subject, and any other built-in test such as a memory and microprocessor self-test. The self-test is

indicated on the headset indicator LED lights. The clinician makes a determination of whether the self-test has failed by noting the indication light (block 108). If failed, the clinician removes the headset from the infant's head and reconnects the headset to a hospital device to evaluate the cause of the failure (block 110). For instance, the headset may provide a more detailed explanation of the failure over the interface.

[0049] If in block 108 the self-test was deemed a pass, then the clinician uses the scanning wand to scan in a patient ID code from the subject (block 112). The headset responds by storing this ID for tagging to the screening test data, which is then taken in accordance to a predetermined test protocol, typically a series of auditory tones with data stored after each tone. Once the test is complete, the headset so indicates by illuminating an appropriate LED light. The clinician waits an appropriate interval for the predetermined test protocol (block 114) and then makes a determination as to whether the test complete light has illuminated within an appropriate interval (block 116). If not complete in block 116, then the clinician may return to block 106, perhaps after confirming good electrode contacts, to reaccomplish the self-test and screening test.

[0050] If test complete in block 116, then the headset is removed from the infant subject's head and the used electrode pads are removed from the electrode arms (block 118). If another subject is to be tested prior to uploading screening test data, then the process returns to block 102, else as depicted the headset is reconnected to the hospital computer (block 120), which recharges the headset (block 122) and also provides an opportunity to activate an Internet connection to initiate data upload and any new test protocol download (block 124).

[0051] The remote user performs diagnostic analysis on the received screening test data to see if the ERP data is indicative of dyslexia (block 126). If a determination is made that the results are not positive for dyslexia (block 128), then the appropriate recipient is informed, such as the parent or the attending pediatrician or obstetrician (block 130). If positive in block 128, then the test results may be advantageously forwarded to an in-network referral physician, such as a neuropsychologist (block 132).

[0052] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art.

[0053] For example, although a headset 10 and distributed dyslexia screening test system 70 have been illustrated that have certain advantages, all of the functionality may be incorporated into a headset. Alternatively, a disposable headset may be used with most of the active components and processing connected thereto. As yet a further alternative, a general-purpose computer may be configured to perform the testing protocol and/or the waveform analysis with the headset including essentially only electrodes and speakers.

[0054] As another example, although screening of infants is advantageously emphasized herein, older children and adults may be advantageously tested as well.

[0055] As yet an additional example, although dyslexia is a condition discussed herein, it will be appreciated that other neurological conditions may advantageously be tested by a similar headset with a frame positioning electrodes in a desired position and configuration. Examples include autism, hearing loss, schizophrenia, etc.

[0056] What is claimed is:

Claims

1. a screening device, comprising:
a frame shaped to be engageable to a head between a reference location, at least one ear and an auditory processing location;
a reference electrode attached to the frame at the reference location;
a signal electrode attached to the frame at the auditory processing location;
an auditory signal producer; and
an Evoked Response Potential (ERP) data processor operably configured to initiate an auditory signal from the auditory signal producer and to perform a signal processing operation on an ERP signal sensed across the reference and signal electrodes.

2. The screening device of claim 1, further comprising a test subject identification device, the ERP data processor further operably configured to associate a test subject identification with the ERP signal.

3. The screening device of claim 2, wherein the test subject identification device comprises a barcode scanner.

4. The screening device of claim 1, further comprising a diagnostic analyzer operably configured to characterize the ERP signal and to compare the characteristics to a predetermined dyslexic ERP characteristic.

5. The screening device of claim 4, further comprising a communication link, wherein the diagnostic analyzer is coupled to frame via the communication link.

6. The screening device of claim 1, wherein the ERP data processor comprises a control module integral to the frame.

7. The screening device of claim 1, wherein the frame includes a disposable portion that includes the electrodes.

8. The screening device of claim 1, whcrcin the ERP data processor includes digital storage configured to store the ERP data.

9. The screening device of claim 2, wherein the ERP data processor is further operably configured to perform a sequence of screening tests, and to store in the digital storage ERP data associated with each test.

10. The screening device of claim 8, wherein the digital storage further includes a predetermined test protocol.

11. The screening device of claim 1, wherein the ERP data processor is further operably configured to generate a user indication of a test condition.

12. The screening device of claim 1, wherein the frame is operably shaped to connect between the ears across a front portion of a patient's head.

13. A method of diagnosing dyslexia, comprising:

positioning a device on a head of an infant, the device positioning a reference electrode and a signal electrode;

generating an auditory stimulus;

recording an Evoked Response Potential (ERP) data across the reference and signal electrodes.

14. The method of claim 13, wherein recording the ERP data further comprising:

storing the ERP data on the device;

connecting the device to a data analyzer;

transmitting the stored ERP data to the data analyzer.

15. The screening device of claim 1, wherein positioning the device on the head of the infant further comprising positioning the infant face up and positioning the device across a forward portion of the infant's head.

DEVICE AND METHOD FOR AN AUTOMATED E.E.G. SYSTEM FOR AUDITORY EVOKED RESPONSES

Abstract of the Invention

A dyslexia screening test system suitable for clinical use includes an integrated headset that efficiently and conveniently performs an auditory Evoked Responsc Potential (ERP) test by positioning electrodes about the ears of the subject. An integral control module automatically performs the test, providing simplified controls and indications to the clinician. A number of screening tests that are stored in the headset are periodically uploaded for billing, remote analysis and result reporting.

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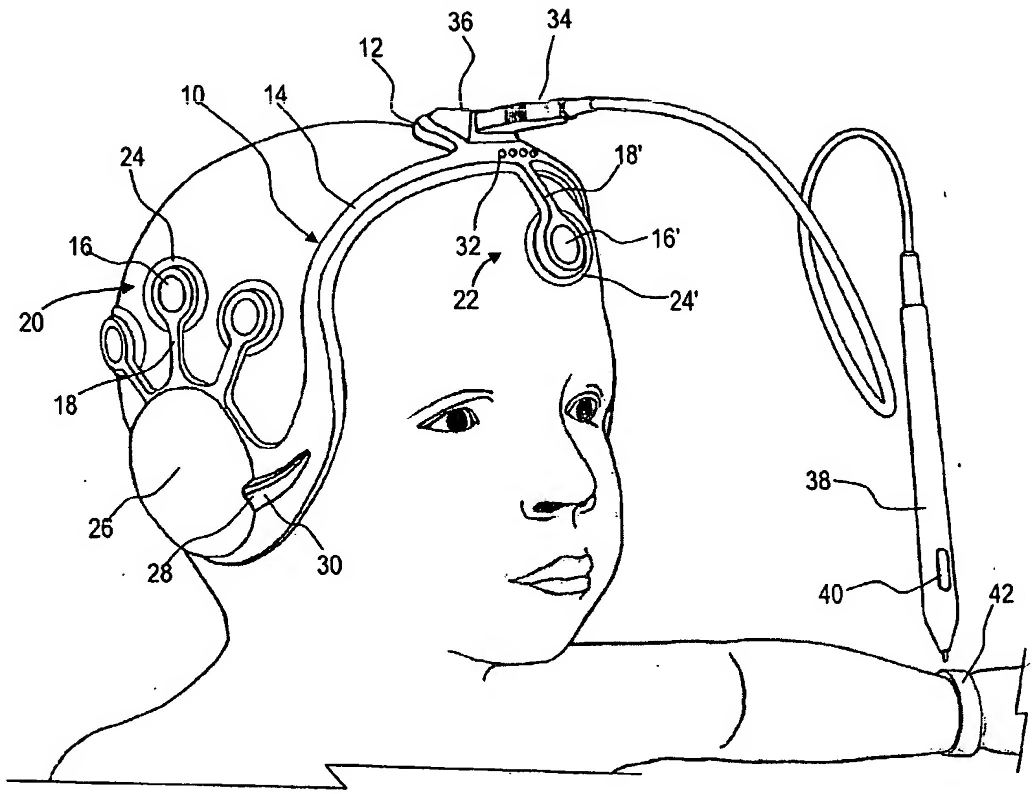

FIG. 1

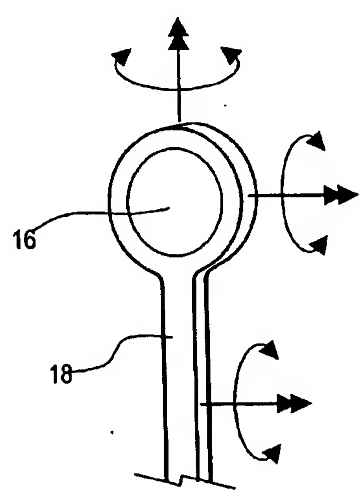

FIG. 2

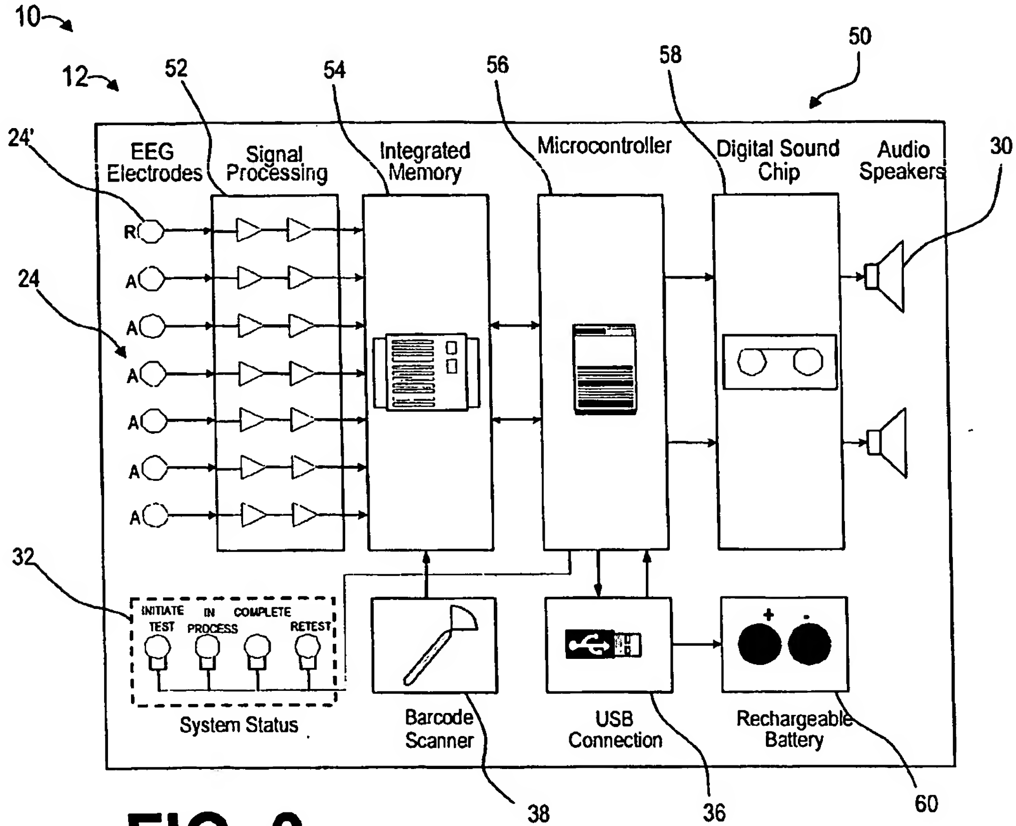
10
12
52
54
56
58
50
24'
EEG Electrodes
Signal Processing
Integrated Memory
Microcontroller
Digital Sound Chip
Audio Speakers
30
24
R
A
32
INITIATE TEST
IN PROCESS
COMPLETE
RETEST
System Status
Barcode Scanner
USB Connection
Rechargeable Battery
38
36
60

FIG. 3

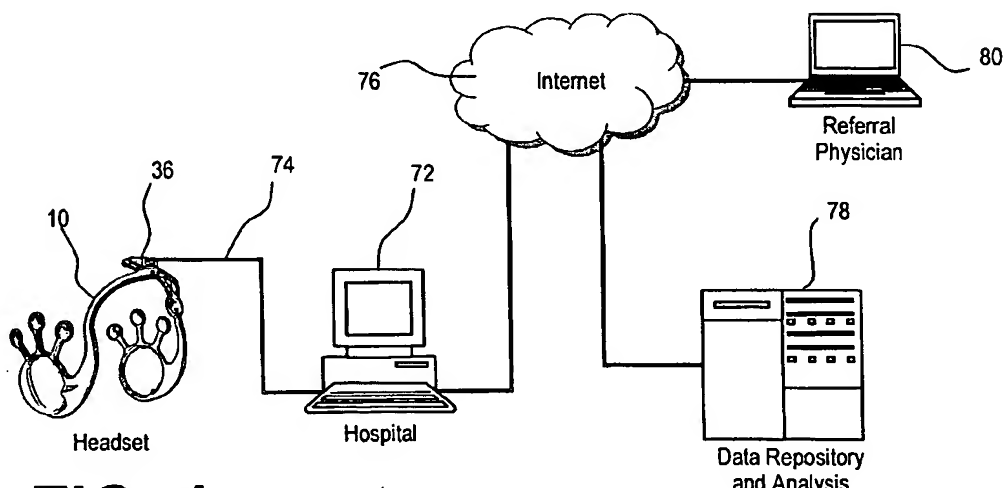
76
Internet
80
Referral Physician
36
74
72
10
78
Headset
Hospital
Data Repository and Analysis

FIG. 4

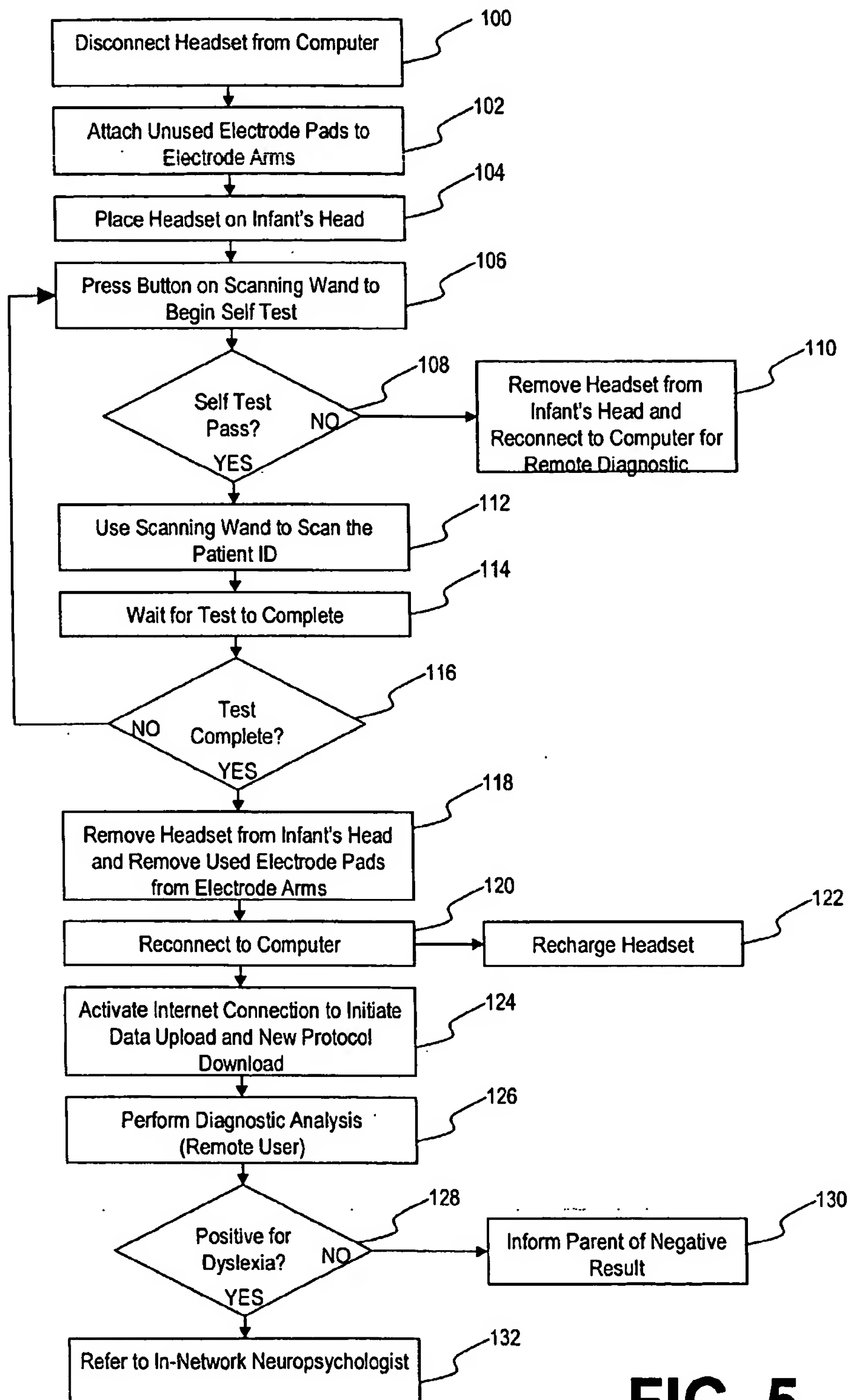
Disconnect Headset from Computer
100
Attach Unused Electrode Pads to Electrode Arms
102
Place Headset on Infant's Head
104
Press Button on Scanning Wand to Begin Self Test
106
Self Test Pass?
NO
YES
108
Remove Headset from Infant's Head and Reconnect to Computer for Remote Diagnostic
110
Use Scanning Wand to Scan the Patient ID
112
Wait for Test to Complete
114
Test Complete?
NO
YES
116
Remove Headset from Infant's Head and Remove Used Electrode Pads from Electrode Arms
118
Reconnect to Computer
120
Recharge Headset
122
Activate Internet Connection to Initiate Data Upload and New Protocol Download
124
Perform Diagnostic Analysis (Remote User)
126
Positive for Dyslexia?
NO
YES
128
Inform Parent of Negative Result
130
Refer to In-Network Neuropsychologist
132

FIG. 5